DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0513]

Electronic Submissions of Food Contact Notifications; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking volunteers to participate in the Food Contact Notification (FCN) Electronic Submissions Pilot Project developed by the Office of Food Additive Safety (OFAS) in the Center for Food Safety and Applied Nutrition (CFSAN). The purpose of the project is to test the efficiency and practicality of a prototype procedure for filing FCNs in electronic format as an alternative to the current paper-based process. FDA believes that this pilot will assist the agency in developing a draft guidance under its good guidance practice (GGP) procedures.

DATES: Submit written requests to participate in the pilot project by [*insert date 30 days after date of publication in the* **Federal Register**]. Comments on this pilot project may be submitted at any time. The pilot is anticipated to last 180 days beginning [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests to participate and comments regarding the pilot project to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Kenneth McAdams, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3392, e-mail: *kenneth.mcadams@cfsan.fda.gov*, or

Kimberly Smeds, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3424, e-mail: kimberly.smeds@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1997, the Food and Drug Administration Modernization Act of 1997 (FDAMA) amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a premarket notification process as the primary method for authorizing new uses of food additives that are ''food contact substances.'' A food contact substance is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' The act further states that the notification process is to be utilized for authorizing the marketing of food contact substances except in instances where the Secretary of Health and Human Services determines that the submission and review of a food additive petition would be necessary to provide adequate assurance of safety, or where FDA and any manufacturer or supplier agree that a petition may be submitted. In the **Federal Register** of May 21, 2002 (67 FR 35724), the agency issued a final rule on premarket notification for food contact substances (21 CFR 170.100 through 170.106).

The FCN process has improved the efficiency of the FDA premarket approval of new food contact substances. More than 200 FCNs have become effective since the process began. FDA FORM 3480 currently provides the format by which information submitted in an FCN is organized to facilitate review by the agency. In order to further improve the efficiency of the FDA premarket approval of new food contact substances, FDA is developing a procedure to allow for the submission of FCNs in electronic format. This procedure includes the use of a software tool to assist a notifier in assembling an FCN. The present pilot project represents the final phase of the agency's development of the software tool for FCN submissions prior to FDA's announcing the availability of such a tool and accompanying guidance in accordance with the agency's GGPs under 21 CFR 10.115. FDA is initiating this pilot to obtain useful feedback during this initial phase in order to maximize efficiency and practicality of the electronic submission process before making it available to the general public for comment.

After completion of the pilot, FDA expects to issue guidance to the public for the electronic filing of FCNs in accordance with GGPs under 21 CFR 10.115.

II. Pilot Project Description

Due to the fact that a limited number of voluntary participants will be needed for the pilot, FDA will use its discretion in selecting the volunteers based on their previous experience in filing FCNs and on the number of FCNs they expect to file during the pilot. The sponsors who participate in the pilot will be asked to submit at least four FCNs in an electronic format during the pilot, using the procedure being tested. Existing regulatory requirements for the submission of FCNs will not be waived, suspended, or modified for the purposes of this pilot project.

The procedure uses an electronic fillable portable document format (PDF) version of FDA FORM 3480 that serves as an organizational backbone to which notifiers may attach studies, data, and other information in electronic format via a software package provided by the agency. It is designed to enable the notifier to submit all the items that constitute a complete FCN in a prescribed structure, removing the need for pagination and providing definitive locations within a set file structure for each type of information, so that the agency in turn can more efficiently review the submission. Pilot participants will be asked to use the procedure and software tool to submit FCNs electronically, and to provide feedback on the process to FDA. Because the process of receiving electronic submissions will be under development during the pilot, FDA will require that participants submit a signed paper copy of each submission along with the electronic version. The paper copy will serve as the official copy under existing regulations during the pilot project. FDA will provide written instructions to individual participants on using the software tool, on assembling and submitting an electronic FCN, and on how to provide feedback. Feedback from pilot participants will assist the agency in improving the software tool and completing development of the procedure.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of

this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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